

**UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

Kathleen Biesterfeld, individually,	)	
and as representative of N.B.; and	)	
Ronald Biesterfeld,	)	
	)	
Plaintiffs,	)	Case No. 1:21-CV-03085
	)	
v.	)	
	)	Judge Edmond E. Chang
Ariosa Diagnostics, Inc.; Ariosa	)	
Diagnostics Clinical Laboratory;	)	
and Harmony Prenatal Testing,	)	
	)	
Defendants.	)	

**MEMORANDUM OPINION AND ORDER**

This case is about the representations—or alleged misrepresentations—of the accuracy rate of prenatal genetic testing, specifically the Harmony Prenatal Test. Kathleen Biesterfeld and Ronald Biesterfeld (along with their child N.B.) filed this lawsuit against Ariosa Diagnostics, Inc., on various consumer-products liability theories. R. 1-1 Compl.<sup>1</sup> ¶

When the Biesterfelds were pregnant with their son, they partook in genetic testing using the Harmony Prenatal Test. Compl. ¶ 6. The Biesterfelds alleged that, based on representations that the Defendants made about the reliability of the test’s ability to “detect chromosomal abnormalities including Trisomy 21” (the anomaly

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<sup>1</sup>The Court has diversity jurisdiction under 28 U.S.C. § 1332. The Plaintiffs are Illinois citizens, R. 30, whereas the sole defendant (after the Plaintiffs dropped the non-legal-entities, R. 19) is a Delaware corporation with its principal place of business in California. R. 1, Not. of Removal ¶ 11. Citations to the docket are indicated by “R.” followed by the docket entry.

associated with Down Syndrome), the Biesterfelds believed that this test would “safely and easily test the fetal DNA of [N.B.] for Down Syndrome and other genetic abnormalities.” *Id.* ¶¶ 7, 9. As a result of the test, the Biesterfelds were under the impression that their son did not have Down Syndrome. *Id.* ¶ 10. To their surprise, when their son was born, he “presented with clear signs of Down Syndrome. *Id.* ¶ 12.

The Biesterfelds now bring several Illinois state law claims against the Defendants. The Defendants (for convenience’s sake, collectively referred to as Ariosa) seek dismissal of the claims. R. 13, Defs.’ Mot. to Dismiss. For the reasons discussed in this Opinion, Ariosa’s motion to dismiss is granted and the Biesterfelds’ claims are dismissed. But the dismissal is without prejudice to file an amended complaint, in light of the absence of any prior amendments and given the additional facts that the Biesterfelds apparently are prepared (based on what they said in the response brief) to include in an amended complaint.

## **I. Background**

In evaluating the motion to dismiss, the Court “must accept as true all of the factual allegations contained in the complaint.” *Erickson v. Pardus*, 551 U.S. 89, 94 (2007). The Biesterfelds used the Harmony Prenatal Test when Kathleen Biesterfeld was pregnant with N.B. Compl. ¶ 6. The Biesterfelds allege that Ariosa represented that the test “would safely and easily target the fetal DNA ... for Down syndrome and other genetic abnormalities.” *Id.* ¶ 7. Specifically, the Biesterfelds assert that Ariosa represented that the Harmony Prenatal Test “had a 100% accuracy rate in detecting abnormalities of Trisomy 21.” *Id.* ¶ 58; *see id.* ¶ 9, Exh. A (screenshot of Ariosa’s

online advertisement). The Biesterfelds moved forward with the Harmony Prenatal Test specifically because of those representations. *Id.* ¶ 39. The Biesterfelds further allege that, because of the perceived accuracy of the Harmony Prenatal Test, they did not seek out any additional testing to detect Trisomy 21 anomalies. *Id.* ¶ 40.

When the Biesterfelds used the Harmony Prenatal Test, in July 2017, the results showed that their son had less than a 0.1% chance of having the Trisomy 21 chromosomal anomaly. *Id.* ¶ 10. But the Biesterfelds' son was born with Down Syndrome. *Id.* ¶ 12. The Plaintiffs now allege that Ariosa made the following misrepresentations about the Harmony Prenatal Test:

- A. Misrepresenting that Harmony Prenatal Test is safe, fit, effective, and adequate for human use in detecting Down Syndrome;
- B. Misrepresenting that Harmony Prenatal Test had a 100% accuracy rate in detecting Trisomy 21 abnormalities;
- C. Misrepresenting the limitations of and alternatives to Harmony Prenatal Test;
- D. Misrepresenting that Harmony Prenatal Test is more accurate than traditional first trimester screening tests;
- E. Misrepresenting that fetal DNA was being tested when, in actuality, only placental DNA was being tested;
- F. Misrepresenting the probability and rate at which the Harmony Prenatal Test could produce false negative results; and
- G. Using deceptive advertising to create the image, impression and belief by consumers and physicians that the use of Harmony Prenatal Test was safe,

reliable, and effective for detecting fetal chromosomal abnormalities, and having no reasonable grounds to believe such representations to be true.

*Id.* ¶ 15, 34. The Biesterfelds bring their claims under the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/2, as well as common law fraud, breach of express warranty, breach of implied warranty of merchantability, and negligence. Compl.

## II. Standard of Review

Under Federal Rule of Civil Procedure 8(a)(2), a complaint generally need only include “a short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a)(2). This short and plain statement must “give the defendant fair notice of what the claim is and the grounds upon which it rests.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (cleaned up).<sup>2</sup> The Seventh Circuit has explained that this rule “reflects a liberal notice pleading regime, which is intended to ‘focus litigation on the merits of a claim’ rather than on technicalities that might keep plaintiffs out of court.” *Brooks v. Ross*, 578 F.3d 574, 580 (7th Cir. 2009) (quoting *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 514 (2002)).

“A motion under Rule 12(b)(6) challenges the sufficiency of the complaint to state a claim upon which relief may be granted.” *Hallinan v. Fraternal Order of Police of Chi. Lodge No. 7*, 570 F.3d 811, 820 (7th Cir. 2009). “A complaint must contain

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<sup>2</sup>This Opinion uses (cleaned up) to indicate that internal quotation marks, alterations, and citations have been omitted from quotations. See Jack Metzler, *Cleaning Up Quotations*, 18 Journal of Appellate Practice and Process 143 (2017).

sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (cleaned up). These allegations “must be enough to raise a right to relief above the speculative level.” *Twombly*, 550 U.S. at 555. The allegations that are entitled to the assumption of truth are those that are factual, rather than mere legal conclusions. *Iqbal*, 556 U.S. at 678–79.

### **III. Analysis**

#### **A. Fraud Claims**

##### **1. Consumer Fraud & Deceptive Business Practices Act**

The Illinois Consumer Fraud and Deceptive Business Practices Act requires that plaintiffs adequately allege (1) a deceptive act or practice by the defendant; (2) the defendant’s intent that the plaintiff rely on the deception; (3) that the deception occurred in the course of conduct involving trade or commerce; (4) actual damage to the plaintiff; and (5) that the actual damage was proximately caused by the deception. *Camasta v. Jos. A. Bank Clothiers, Inc.*, 761 F.3d 732, 739 (7th Cir. 2014).

The key allegedly deceptive statement at issue is that Harmony Prenatal Test was represented to have a “100% accuracy rate” in detecting Trisomy 21. Compl. ¶ 58; R. 22, Pls.’ Resp. at 1–2. The defense first argues that the Biesterfelds have pleaded themselves out of court, because they also allege that, after processing the Biesterfelds’ submission, Ariosa generated a report “indicating” that the chances of the Trisomy 21 anomaly was less than 0.1%. Compl. ¶ 10. To the defense’s way of thinking, the statement in the report precluded the Plaintiffs, as a matter of law, from

reasonably relying on the 100% accuracy-rate statement. Defs.’ Mot. to Dismiss at 6–7. The defense goes on to argue that the website advertisement that the Plaintiffs allegedly relied on is “wholly consistent with the report plaintiffs claim Ariosa generated.” *Id.* at 7. Ariosa points out that the screenshot also “describes the Harmony Prenatal Test’s Trisomy 21 detection rate as ‘[m]ore than 99 in 100’” and also cites to a medical-journal article as the source for that information. *Id.* In their reply, Ariosa raises an additional argument that the statement “Harmony had a 100% trisomy 21 detection rate compared to 79% with traditional screening” was “written in past tense” (focusing on the past-tense verb “had”) and thus “cannot reasonably be construed to suggest what plaintiffs claim—a future promise that Harmony Prenatal Test will detect Trisomy 21 abnormalities with 100% accuracy.” R. 26, Defs.’ Reply at 4.

That fine-tooth reading of the 100% detection-rate statement is much too crabbed and nuanced at the pleading stage. At this stage of the litigation, the Plaintiffs are entitled to the interpretation of the allegations in the light most favorable to them and to the benefit of reasonable inferences. It is reasonable to infer that Ariosa intended for consumers to rely on the statement at issue. If this case moves forward, then discovery will test whether reasonable consumers would interpret the statement that “Harmony had a 100% trisomy 21 detection rate” as a past-tense reference to a small-point-font note referring to a medical journal—or instead as a representation that the test would yield a 100% detection rate.

Where the Fraud Act claim does flounder, however, are two statutory requirements: first, the allegedly deceptive statements must happen “in the conduct of any trade or commerce.” 815 ILCS 505/2. The terms trade and commerce do cover advertising or, even more broadly, the offering of services for sale. 815 ILCS 505/1(f) (defining the terms “trade” and “commerce”). The second statutory requirement is that, typically, a Fraud Act plaintiff must allege that she is a “consumer” in order to successfully allege a claim. *See* 815 ILCS 505/1(2) (defining “consumer” as “any person who purchases or contracts for the purchase of merchandise not for resale in the ordinary course of his trade or business but for his use or that of a member of his household”). Whether the allegedly deceptive statements happened in the conduct of trade or commerce, and whether the Biesterfelds were “consumers” for purposes of the Fraud Act is not at all apparent on the current complaint.

In the current complaint (or more accurately, *not* in the current complaint), there are key gaps and unanswered questions about how the Plaintiffs came to use this particular genetic test. Was it offered to them by a doctor or did the Biesterfelds order this test on their own? No answer; just the Plaintiffs “utilized” the test. Compl. ¶ 6. Did the Biesterfelds pay for this test out of pocket or was it covered by insurance, or was it in effect costless as part of some other coverage? Again, no answer; just the Plaintiffs “utilized” the test. *Id.* Did the Biesterfelds themselves actually see the crucial online advertising? No answer; instead, the Complaint just attaches the online advertisement “from May 2018”—after N.B. was born. *Id.* ¶ 9. Without allegations on these points, the Complaint fails to adequately state a Fraud Act claim.

In addition to the flaws with those two elements, the Complaint also fails to adequately allege that the damages that they suffered were proximately caused by the alleged misrepresentations. *See Camasta*, 761 F.3d at 739 (successful Fraud Act claim must allege proximately caused damages). In the current version of the Complaint, the Biesterfelds generally allege that they “sustained injuries, harm, and economic loss for the past, present, and future.” Compl. ¶ 21. But the Complaint does not actually draw a connection between the misrepresentations and the injuries they have suffered (whatever they are). It is not until their response brief that the Plaintiffs set forth actual *factual* allegations (rather than conclusions). Pls.’ Resp. at 6. The Biesterfelds explain that they would have terminated the pregnancy had they known that the test was not 100% effective. *Id.* That might very well satisfy the damages element; in essence, damages arising out of a so-called wrongful birth could readily include the costs of raising a child and the child’s medical expenses. (The potential also would readily exceed the amount-in-controversy requirement for diversity jurisdiction of \$75,000.) These allegations, along with the allegation that a different genetic test, such as amniocentesis, would have revealed Trisomy 21, must be repleaded in an amended complaint in order to be considered. So the current version of the Complaint must be dismissed, but leave is granted to file an amended complaint.

## **2. Common Law Fraud**

The same goes for the common law fraud claim, that is, the current version of the Complaint is insufficient, but the Plaintiffs may file an amended complaint. To successfully plead an Illinois common law fraud claim, the plaintiff must adequately



allege that (1) the defendant made a false statement of material fact; (2) the defendant knew that the statement was false; (3) the defendant made the statement intending to induce the plaintiff to act; (4) the plaintiff relied on the truth of the statement; and (5) the plaintiff's damages resulted from that reliance. *Connick v. Suzuki Motor Co. Ltd.*, 675 N.E.2d 584, 591 (Ill. 1996).

Common law fraud is distinct from the Fraud Act in that it requires the Biesterfelds to plead that Ariosa knew that the alleged misrepresentations were false and that the Biesterfelds did in fact rely on the statements. *Connick*, 675 N.E.2d 584 at 591; see *Castlerigg Master Investments, Ltd. v. AbbVie, Inc.*, 2021 WL 1213171, at \*4 (2021) (“In order to adequately plead reliance [plaintiff] needed to detail its reliance upon the defendant’s actions and words with sufficient specificity and particularity.”) (cleaned up). Yes, the Plaintiffs do allege that Ariosa knew that the misrepresentations were false. Compl. ¶ 36. But like the defects in the Fraud Act allegations, however, even what precise misrepresentations the Biesterfelds themselves read about, heard from others, and relied on is not clear. Instead, the Plaintiffs list a slew of misrepresentations, Compl. ¶ 34(A)–(F), without then actually alleging the context in which they *themselves* learned of the misrepresentations and how the Plaintiffs relied on them. Again, the screenshot that the Biesterfelds attached to their complaint, which reflects the “had a 100% trisomy 21 detection rate” assertion, is from May 2018—three months after the birth of N.B. Compl. ¶ 10; R. 1-1, Exh. A. The Biesterfelds explain—in their response brief—that they did view the website before moving forward with the Harmony Prenatal Test and that, at the time of their

decision, the website had this same advertisement. R. 22, Pls.' Resp. at 6. But that is not in the current version of the Complaint. So the common law fraud claim is dismissed, though without prejudice to the filing of an amended complaint.

### **3. Rule 9(b)**

The defense also argues the Biesterfelds have failed to meet the heightened pleading standard of Civil Rule 9(b) which requires that a plaintiff "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b); *Pirelli Armstrong Tire Corp. Retiree Medical Benefits Trust v. Walgreen Co.*, 631 F.3d 436, 441 (7th Cir. 2011); Defs.' Br. at 7–8. To satisfy this requirement, the plaintiff must describe the "who, what, when, where, and how" of the fraud. *Pirelli*, 631 F.3d at 442–43.

It is true that the gaps in the Fraud Act and common law fraud claims, as discussed earlier, in part represent failures to plead the claims with particularity (to the extent that the Fraud Act claims sound in fraud, though they do not need to). What misrepresentations were made to the Plaintiffs, and when, and in what context, are all important facts that must be pleaded with particularity. So the claims must be repleaded in any event. Having said that, other contentions advanced by Ariosa are not necessarily fatal to the claims and would satisfy the particularity for purposes of Rule 9(b).

For example, this is not the type of fraud case in which the Plaintiffs can be expected to identify the names of the Ariosa employees, whether in the marketing department or elsewhere, who wrote the statements at issue. But *someone* (or some

person) decided to write the statements in the way that they did, including the “had a 100% trisomy 21 detection rate” statement—it was on Ariosa’s website. It is not as if, as it is with other vaguely alleged fraud schemes, Ariosa would be at a loss trying to figure out the source of the detection-rate statement. Also, for particularity-standard purposes, it is reasonable to infer that this kind of statement is one that a reasonable customer seeking out prenatal genetic testing would readily rely on. So, although the Biesterfelds must amend their complaint to include the facts and allegations contained in the response brief, as well as address the other questions raised above, it is quite possible that the Rule 9(b) heightened pleading standard will be satisfied.

### **B. Breach of Warranty**

To state a claim for breach of express warranty under Illinois law, a plaintiff must adequately allege: “(1) the terms of the warranty; (2) a breach or failure of the warranty; (3) a demand upon the defendant to perform under the terms of the warranty; (4) a failure by the defendant to do so; (5) compliance with the terms of the warranty by the plaintiff; and (6) damages measured by the terms of the warranty.” *Lambert v. Dollar Gen. Corp.*, 2017 WL 2619142, at \*2 (N.D. Ill. June 16, 2017). To state a claim for breach of the implied warranty of merchantability (as distinct from an express warranty) (as distinct from an express warranty) under Illinois law, a plaintiff must allege that (1) the defendant sold goods that were not merchantable at the time of sale; (2) the plaintiff suffered damages as a result of the defective goods; and (3) the plaintiff gave the defendant notice of the defect. *Lambert*, 2017 WL

2619142, at \*4. To be merchantable, the goods must be “fit for the ordinary purpose for which the goods are used,” but must also “conform to the promises or affirmations of fact made on the container or label if any.” 810 ILCS 5/2-314(2)(c), (2)(f). If a plaintiff seeks to recover purely economic damages, then the plaintiff must also show that he is in vertical privity with the seller. *Jensen v. Bayer AG*, 862 N.E.2d 1091, 1099 (Ill. App. Ct. 2007).

Both of the warranty claims must be dismissed (though again without prejudice this time). On the express-warranty claim, the Biesterfelds have not alleged that they demanded Ariosa fulfill the terms of the warranty, that Ariosa refused to comply after the demand, or that the Plaintiffs themselves complied with the warranty terms. None of those elements are pleaded. Indeed, the Plaintiffs also have not pleaded any information on whether they purchased the test or how they came to obtain the test in the first place. Yet an express-warranty claim required privity of contract with Ariosa or, at the least, some exception for privity of contract as the “ultimate consumer.” See *Rosenstern v. Allergan, Inc.*, 987 F.Supp.2d 795, 805 (N.D. Ill. 2013) (“The exception to this rule is if a manufacturer ‘expressly warranted its goods to the ultimate consumers and this was the basis for the bargain relied upon by plaintiffs.’”). Ultimately, the factual setting presented by the Biesterfelds on the prenatal test does not seem to give rise to a warranty claim at all. It is not as if Ariosa can supply the Plaintiffs with the 100% detection-rate version of the Harmony test—it does not exist. Put another way, the alleged facts might give rise to a Fraud Act

claim, a common law fraud claim, or a breach of contract claim (if the Plaintiffs actually entered into a contract with Ariosa). But a warranty claim does not seem to fit.

The same goes for the claim for breach of implied warranty of merchantability. Here, the Biesterfelds also failed to plead how they are in vertical privity with Ariosa or why the privity requirement otherwise should not apply. *See Szajana v. General Motors Corp.*, 503 N.E.2d 760, 767 (Ill. 1986) (declining “to abolish the privity requirement in implied-warranty economic-loss cases.”); *see also Board of Educ. of City of Chicago v. A, C and S, Inc.*, 546 N.E.2d 580, 595 (Ill. 1985) (holding that the privity requirement is relaxed only when the non-economic loss alleged is physical harm to a person). This form of warranty claim is also dismissed, without prejudice for now.

### **C. Negligence**

Under Illinois law, as in many States, a successful negligence claim requires the plaintiff to show the existence of a duty, the breach of that duty, and injury proximately caused by the breach, and damages resulting from the breach. *Horne v. Electric Eel Mfg. Co., Inc.*, 987 F.2d 704, 725 (7th Cir. 2021). Many of the same gaps that required dismissal of the prior claims signal the demise of this claim as well. The Complaint has no allegations at all about how a duty arose from the relationship (whatever the contours of that relationship are) between the Plaintiffs and Ariosa. And the damages caused by the alleged breach are also left unalleged (that is, until the response brief). This claim too must be dismissed, and when more facts are added to the amended complaint (if one is filed), then the defense can renew its challenge to

the claim if appropriate. The Court then will be in a better position to assess the negligence claim.

#### **IV. Conclusion**

The motion to dismiss the current Complaint is granted. For now the dismissal is without prejudice. The Biesterfelds may file a First Amended Complaint to try to fix the problems by April 20, 2022. If no new complaint is filed by that deadline, then the dismissal of the Complaint will convert to a dismissal with prejudice. The tracking status hearing of April 8, 2022, is reset to April 29, 2022, at 8:30 a.m., but to track the case only (no appearance is required).

ENTERED:

s/Edmond E. Chang  
Honorable Edmond E. Chang  
United States District Judge

DATE: March 31, 2022